Application No.: 10/616,776

Office Action Dated: April 19, 2006

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

A pharmaceutical dosage unit comprising an effective

This listing of claims will replace all prior versions, and listings, of claims in the application. Listing of Claims:

1-48. (canceled)

49. (Currently amended)

amount of modafinil wherein at least about 10% of the total cumulative modafinil particles are smaller than about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns in diameter, wherein said

pharmaceutical dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the particles have diameters less than about 200 microns, and said dosage unit

comprises modafinil particles from at least one small particle discrete lot and modafinil

particles from at least one large particle discrete lot.

50. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 15% of the total cumulative modafinil particles are smaller than or equal to about 25 microns

in diameter and more than about 5% of the total cumulative particles are more than about 200

microns.

51. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about

20% of the total cumulative modafinil particles are smaller than or equal to about 25 microns

in diameter and more than about 5% of the total cumulative particles are more than about 200

microns.

52. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about

25% of the total cumulative modafinil particles are smaller than or equal to about 25 microns

in diameter and more than about 5% of the total cumulative particles are more than about 200

microns.

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53. (Previously presented) The pharmaceutical dosage unit of claim 49 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

54. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

55. (Original) The pharmaceutical dosage unit of claim 50 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

56. (Original) The pharmaceutical dosage unit of claim 51 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

57. (Original) The pharmaceutical dosage unit of claim 52 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

58. (Previously presented) The pharmaceutical dosage unit of any one of claims 49-52 wherein the amount of modafinil is about 100 mg.

- 59. (Previously presented) The pharmaceutical dosage unit of any one of claims 49-52 wherein the amount of modafinil is about 200 mg.
- 60. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 10% of the total cumulative particles are more than about 200 microns.
- 61. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 10% of the total cumulative particles are more than about 200 microns.
- 62. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

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63. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about

10% of the total cumulative particles are more than about 200 microns.

64. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about

10% of the total cumulative particles are more than about 200 microns.

65. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about

15% of the total cumulative particles are more than about 200 microns.

66. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about

15% of the total cumulative particles are more than about 200 microns.

67. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about

15% of the total cumulative particles are more than about 200 microns.

68. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about

15% of the total cumulative particles are more than about 200 microns.

69. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about

15% of the total cumulative particles are more than about 200 microns.

70. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about

20% of the total cumulative particles are more than about 200 microns.

71. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about

20% of the total cumulative particles are more than about 200 microns.

72. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about

20% of the total cumulative particles are more than about 200 microns.

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73. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about

20% of the total cumulative particles are more than about 200 microns.

74. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about

20% of the total cumulative particles are more than about 200 microns.

75. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about

25% of the total cumulative particles are more than about 200 microns.

76. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about

25% of the total cumulative particles are more than about 200 microns.

77. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about

25% of the total cumulative particles are more than about 200 microns.

78. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about

25% of the total cumulative particles are more than about 200 microns.

79. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about

25% of the total cumulative particles are more than about 200 microns.

80. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about

30% of the total cumulative particles are more than about 200 microns.

81. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about

30% of the total cumulative particles are more than about 200 microns.

82. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about

30% of the total cumulative particles are more than about 200 microns.

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83. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

84. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

85. (Original) The pharmaceutical dosage unit of any one of claims 60-84 wherein the amount of modafinil is about 100 mg.

86. (Original) The pharmaceutical dosage unit of any of claims 60-84 wherein the amount of modafinil is about 200 mg.

87-132. Canceled.

133. (Previously presented) An oral dosage unit according to claim 86, that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.

134. (Currently amended) An oral dosage unit of modafinil comprising solid modafinil particles, wherein more than about 5% of the modafinil particles in the dosage unit have diameters greater than 220 microns, and said dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the particles have diameters less than about 200 microns and said dosage unit comprises modafinil particles from at least one small particle discrete lot and modafinil particles from at least one large particle discrete lot.

135. (Previously presented) An oral dosage unit according to claim 134, wherein less than about 35% of the total cumulative number of particles are more than 220 microns in diameter.

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136. (Previously presented) An oral dosage unit according to claim 135, wherein between about 10% to about 30% of the total cumulative number of particles are more than 220 microns in diameter.

137. (Previously presented) An oral dosage unit according to any one of claims 134 to 136, wherein said dosage form contains 100 mg of modafinil, and is bioequivalent to a 100 mg modafinil dosage unit in which at least about 95% of the particles are smaller than about 200 microns.

138. (Previously presented) An oral dosage form according to any one of claims 134 to 136, wherein said dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg modafinil dosage form in which at least about 95% of the particles are smaller than about 200 microns.

- 139. (Previously presented) An oral dosage form according to claim 138 that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.
- 140. (Previously presented) A method of treating a condition using modafinil, the method of treating comprising:

providing an oral dosage unit according to claim 134.

- 141. (Previously presented) A method according to claim 140, wherein said condition comprises one or more of narcolepsy and idiopathic hypersomnia.
- 142. (Previously presented) A method of treating a mammal diagnosed with a modafinil-responsive disease or condition selected from the group consisting of narcolepsy, sleepiness, excessive sleepiness, excessive daytime sleepiness associated with narcolepsy, Parkinson's disease, urinary incontinence, multiple sclerosis fatigue, ADHD, Alzheimer's disorder, sleep apnea, obstructive sleep apnea, depression, and ischemia, said method

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comprising administering to said mammal one or more oral unit doses according to any one of claims 134 to 136.

- 143. (Previously presented) A method according to claim 142 wherein said dosage form contains 100 mg of modafinil, and is bioequivalent to a 100 mg modafinil dosage unit in which at least about 95% of the particles are smaller than about 200 microns.
- 144. (Previously presented) A method according to claim 142 wherein said dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg modafinil dosage form in which at least about 95% of the particles are smaller than about 200 microns.
- 145. (Previously presented) A method according to claim 144 that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.